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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEVADA

AMARIN PHARMA, INC. and AMARIN PHARMACEUTICALS IRELAND LIMITED,

Plaintiffs,

v.

ROXANE LABORATORIES, INC. and HIKMA PHARMACEUTICALS PLC,

Defendants.

Case No.: 2:16-cv-02525

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Limited (collectively, "Plaintiffs" or "Amarin"), by their attorneys, for their complaint against Roxane Laboratories,

Inc. ("Roxane") and Hikma Pharmaceuticals PLC ("Hikma") (collectively, "Defendants") allege as follows:

Nature of the Action

1. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, and in particular under 35 U.S.C. § 271(a-c, e) for infringement of U.S. Patent No. 8,293,728 ("the '728 Patent"), U.S. Patent No. 8,318,715 ("the '715 Patent"), U.S. Patent No. 8,357,677 ("the '677 Patent"), U.S. Patent No. 8,367,652 ("the '652 Patent"), U.S. Patent No. 8,377,920 ("the '920 Patent"), U.S. Patent No. 8,399,446 ("the '446 Patent"), U.S. Patent No. 8,415,335 ("the '335 Patent"), U.S. Patent No. 8,426,399 ("the '399 Patent"), U.S. Patent No. 8,431,560 ("the '560 Patent"), U.S. Patent No. 8,440,650 ("the '650 Patent"), U.S. Patent No. 8,518,929 ("the '929 Patent"), U.S. Patent No. 8,524,698 ("the '698 Patent"), U.S. Patent No. 8,546,372 ("the '372 Patent"), and U.S. Patent No. 8,617,594 ("the '594 Patent"). This action relates to an Abbreviated New Drug Application ("ANDA") No. 209457 filed by or for the benefit of Defendants with the United States Food and Drug Administration ("FDA") for approval to market generic versions of Plaintiffs' VASCEPA® pharmaceutical products that are sold in the United States, including within this judicial district. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

The Parties

2. Plaintiff Amarin Pharma, Inc. is a company organized and existing under the laws of Delaware with its principal place of business at 1430 Route 206, Bedminster, NJ 07921.

3. Plaintiff Amarin Pharmaceuticals Ireland Limited is a company incorporated under the laws of Ireland with registered offices at 88 Harcourt Street, Dublin 2, Dublin, Ireland.

4. Upon information and belief, Defendant Roxane Laboratories, Inc. ("Roxane") is a company organized and existing under the laws of Nevada with its principal place of business at 1809 Wilson Road, Columbus, Ohio.

5. Upon information and belief, Defendant Hikma Pharmaceuticals PLC ("Hikma")

is a company organized and existing under the laws of the United Kingdom with its principal place of business at 13 Hanover Square, London W1S 1HL, United Kingdom.

6. Upon information and belief, Roxane is a wholly owned subsidiary of Hikma.

7. Upon information and belief, Defendants either directly or through one or more of their wholly owned subsidiaries and/or agents, develop, manufacture, distribute, market, offer to sell, and sell generic drug products for sale and use throughout the United States, including within this judicial district.

Jurisdiction and Venue

8. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35 of the U.S. Code, for infringement of the '728 Patent, the '715 Patent, the '677 Patent, the '652 Patent, the '920 Patent, the '446 Patent, the '335 Patent, the '399 Patent, the '560 Patent, the '650 Patent, the '929 Patent, the '698 Patent, the '372 Patent, and the '594 Patent.

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

10. Upon information and belief, Roxane is incorporated in Nevada.

11. On information and belief and as stated in the ANDA Notice Letter, Defendants prepared and filed ANDA No. 209457, through Roxane, with the intention of seeking to market a generic version of Amarin's VASCEPA® product, including within this judicial district.

12. Upon information and belief, Defendants regularly conduct business in Nevada, either directly or through one or more of their wholly owned subsidiaries and/or agents.

13. Upon information and belief, Defendants are licensed to sell generic pharmaceutical products in Nevada, either directly or through one or more of their wholly owned subsidiaries and/or agents.

14. Upon information and belief, Defendants receive Medicaid reimbursements for drugs sold in Nevada, either directly or through one or more of their wholly owned subsidiaries and/or agents.

15. Upon information and belief, Defendants plan to sell a generic VASCEPA® product in Nevada, list a generic VASCEPA® product on Nevada's prescription drug formulary, and seek Medicaid reimbursements for sales of a generic VASCEPA® product in Nevada, either directly or through one or more of their wholly owned subsidiaries and/or agents.

16. On information and belief, by virtue of, *inter alia*, Roxane's incorporation in Nevada, as well as Defendants' sales-related activities in Nevada, including but not limited to the substantial, continuous, and systematic distribution, marketing, and/or sales of pharmaceutical products to residents of Nevada described in paragraphs 11–15, this Court has general personal jurisdiction over Defendants.

17. On information and belief, by virtue of, *inter alia*, Defendants' continuous and systematic contacts with Nevada, including but not limited to the contacts described in paragraphs 11–15, this Court has specific personal jurisdiction over Defendants. These activities satisfy due process and confer personal jurisdiction over Defendants consistent with Nevada law. *See, e.g.*, *Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 762–63 (Fed. Cir. 2016) (holding that minimum-contacts requirement for specific personal jurisdiction is established where Defendant's "ANDA filings and its distribution channels establish that [the Defendant] plans to market its proposed drugs in [the State where the complaint was filed] and the lawsuit is about patent constraints on such in-State marketing.").

18. On the basis of at least the facts alleged in paragraphs 10–17, venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

Regulatory Requirements for New and Generic Drugs

19. A person wishing to market a new drug that has not previously been approved by the U.S. Food and Drug Administration ("FDA") (a "pioneering" drug) must file a New Drug Application ("NDA") with FDA demonstrating that the drug is safe and effective for its intended use. 21 U.S.C. § 355(b).

20. A person wishing to market a generic copy of a drug that previously has been approved by FDA may follow a truncated approval process by filing an Abbreviated New Drug

Application ("ANDA") for a generic version of that drug. In the ANDA, the applicant must demonstrate, among other things, bioequivalence of the generic copy with the pioneering drug. 21 U.S.C. § 355(j)(2)(A)(iv).

21. Unlike an NDA applicant, an ANDA applicant is not required to include safety and effectiveness data. Instead, the ANDA applicant is permitted to rely on the approval of the NDA applicant's drug—in essence, piggybacking on the NDA application and safety and effectiveness conclusions. 21 U.S.C. § 355(j).

22. Nor does an ANDA applicant establish any new conditions of use for the proposed drug product. Instead, an ANDA applicant may seek approval only for conditions of use that previously have been approved in connection with an approved NDA. 21 U.S.C. § 355(j)(2)(A)(i).

The Approved Drug Product

23. Amarin Pharmaceuticals Ireland Limited is the current holder of NDA No. 202057, for 1g icosapent ethyl capsules, which was first approved by FDA on July 26, 2012. Amarin Pharma, Inc. is Amarin Pharmaceuticals Ireland Limited's agent in the United States for purposes of communicating with FDA regarding NDA No. 202057. Amarin Pharmaceuticals Ireland Limited and Amarin Pharma, Inc. market the approved drug product under the tradename VASCEPA®.

24. VASCEPA® is indicated as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. A true, correct, and complete copy of the Prescribing Information for VASCEPA® approved in NDA No. 202057 is attached as Exhibit A.

25. FDA has listed the '728, '715, '677, '652, '920, '446, '335, '399, '560, '650, '929, '698, '372, and '594 Patents in the Orange Book—formally known as Approved Drug Products With Therapeutic Equivalence Evaluations—in connection with NDA No. 202057.

26. Amarin Pharmaceuticals Ireland Limited is the owner of the '728, '715, '677, '652, '920, '446, '335, '399, '560, '650, '929, '698, '372, and '594 Patents.

ANDA No. 209457

27. Upon information and belief, on or before September 21, 2016, Defendants, through Roxane, submitted to FDA an ANDA (ANDA No. 209457) with paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j)(2)(A)(vii)(IV), for 1g icosapent ethyl capsules purportedly bioequivalent to VASCEPA®. The purpose of the ANDA is to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of a generic VASCEPA® product.

28. Upon information and belief, the indication set forth in the proposed labeling submitted in ANDA No. 209457 for the generic VASCEPA® product is to reduce triglyceride levels in adult patients with severe hypertriglyceridemia, *i.e.*, the same indication as that set forth in the approved labeling for VASCEPA®.

29. Upon information and belief, Defendants, through Roxane, sent Amarin a letter dated September 21, 2016, which was received by Amarin on September 22, 2016 (the "Notice Letter"). The Notice Letter represented that Defendants, through Roxane, had submitted to FDA an ANDA, No. 209457, with a paragraph IV certification for the '728, '715, '677, '652, '920, '446, '335, '399, '560, '650, '929, '698, '372, and '594 Patents.

30. Upon information and belief, the purpose of the ANDA and paragraph IV certifications is to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of a generic version of VASCEPA® before the expiration of the patents listed in the Orange Book for NDA No. 202057. Hence, Defendants' purpose in submitting ANDA No. 209457 is to market products described therein before expiration of the '728, '715, '677, '652, '920, '446, '335, '399, '560, '650, '929, '698, '372, and '594 Patents.

31. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

Count I: Patent Infringement of the '728 Patent

32. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 31

above.

33. United States Patent No. 8,293,728, entitled "METHODS OF TREATING HYPERTRIGLYCERIDEMIA," was duly and legally issued by the United States Patent and Trademark Office on October 23, 2012. Plaintiff Amarin Pharmaceuticals Ireland Limited is the owner of the '728 Patent. A true and complete copy of the '728 Patent is attached hereto as Exhibit B.

34. Upon information and belief, Defendants submitted ANDA No. 209457 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of VASCEPA® before the expiration of the '728 Patent.

35. Defendants' manufacture, use, offer for sale, or sale of such product would infringe the claims of the '728 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

36. Upon information and belief, if approved, the generic VASCEPA® product for which approval is sought in Defendants' ANDA No. 209457 will be administered to human patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. This administration by, for example, physicians would constitute direct infringement, either literally or under the doctrine of equivalents, of one or more claims of the '728 Patent. Upon information and belief, this infringement will occur at Defendants' behest, with their intent, knowledge, and encouragement as a result of, for example, Defendants' sales, marketing, and distribution of their ANDA Product as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons, Defendants will actively induce, encourage, aid, and abet administration of the generic VASCEPA® product with knowledge that it is in contravention of Plaintiffs' rights under the '728 Patent.

37. Defendants' manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the generic VASCEPA® product for which approval is sought in ANDA No. 209457 would actively induce and contribute to infringement of the '728 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

38. Upon information and belief, as part of the ANDA filing, Defendants purportedly provided written certification to FDA that the claims of the '728 Patent are invalid and/or will not be infringed by the manufacture, use, or sale of Defendants' generic version of VASCEPA®.

39. Defendants gave written notice of their certification of invalidity and/or non-infringement of the '728 Patent, alleging that claims of the '728 Patent are invalid and/or that certain claims would not be infringed by Defendants' generic version of VASCEPA®, and informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '728 Patent.

40. Defendants have infringed the '728 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 209457 with a paragraph IV certification and seeking FDA approval of ANDA No. 209457 to market a generic version of VASCEPA® prior to the expiration of the '728 Patent. Moreover, if Defendants commercially use, offer for sale, or sell their generic version of VASCEPA®, or induce or contribute to such conduct, they would further infringe the '728 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

41. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to infringement of the '728 Patent. Plaintiffs do not have an adequate remedy at law.

Count II: Patent Infringement of the '715 Patent

42. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 41 above.

43. United States Patent No. 8,318,715, entitled "METHODS OF TREATING HYPERTRIGLYCERIDEMIA," was duly and legally issued by the United States Patent and Trademark Office on November 27, 2012. Plaintiff Amarin Pharmaceuticals Ireland Limited is the owner of the '715 Patent. A true and complete copy of the '715 Patent along with the certificate of correction is attached hereto as Exhibit C.

44. Upon information and belief, Defendants submitted ANDA No. 209457 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of VASCEPA® before the expiration of the '715 Patent.

45. Defendants' manufacture, use, offer for sale, or sale of such product would infringe the claims of the '715 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

46. Upon information and belief, if approved, the generic VASCEPA® product for which approval is sought in Defendants' ANDA No. 209457 will be administered to human patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. This administration by, for example, physicians would constitute direct infringement, either literally or under the doctrine of equivalents, of one or more claims of the '715 Patent. Upon information and belief, this infringement will occur at Defendants' behest, with their intent, knowledge, and encouragement as a result of, for example, Defendants' sales, marketing, and distribution of their ANDA Product as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons, Defendants will actively induce, encourage, aid, and abet administration of the generic VASCEPA® product with knowledge that it is in contravention of Plaintiffs' rights under the '715 Patent.

47. Defendants' manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the generic VASCEPA® product for which approval is sought in ANDA No. 209457 would actively induce and contribute to infringement of the '715 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

48. Upon information and belief, as part of the ANDA filing, Defendants purportedly provided written certification to FDA that the claims of the '715 Patent are invalid and/or will not be infringed by the manufacture, use, or sale of Defendants' generic version of VASCEPA®.

49. Defendants gave written notice of their certification of invalidity and/or non-infringement of the '715 Patent, alleging that claims of the '715 Patent are invalid and/or that

certain claims would not be infringed by Defendants' generic version of VASCEPA®, and informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '715 Patent.

50. Defendants have infringed the '715 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 209457 with a paragraph IV certification and seeking FDA approval of ANDA No. 209457 to market a generic version of VASCEPA® prior to the expiration of the '715 Patent. Moreover, if Defendants commercially use, offer for sale, or sell their generic version of VASCEPA®, or induce or contribute to such conduct, they would further infringe the '715 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

51. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to infringement of the '715 Patent. Plaintiffs do not have an adequate remedy at law.

Count III: Patent Infringement of the '677 Patent

52. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 51 above.

53. United States Patent No. 8,357,677, entitled "METHODS OF TREATING HYPERTRIGLYCERIDEMIA," was duly and legally issued by the United States Patent and Trademark Office on January 22, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the owner of the '677 Patent. A true and complete copy of the '677 Patent is attached hereto as Exhibit D.

54. Upon information and belief, Defendants submitted ANDA No. 209457 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of VASCEPA® before the expiration of the '677 Patent.

55. Defendants' manufacture, use, offer for sale, or sale of such product would infringe the claims of the '677 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

56. Upon information and belief, if approved, the generic VASCEPA® product for

which approval is sought in Defendants' ANDA No. 209457 will be administered to human patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. This administration by, for example, physicians would constitute direct infringement, either literally or under the doctrine of equivalents, of one or more claims of the '677 Patent. Upon information and belief, this infringement will occur at Defendants' behest, with their intent, knowledge, and encouragement as a result of, for example, Defendants' sales, marketing, and distribution of their ANDA Product as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons, Defendants will actively induce, encourage, aid, and abet administration of the generic VASCEPA® product with knowledge that it is in contravention of Plaintiffs' rights under the '677 Patent.

57. Defendants' manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the generic VASCEPA® product for which approval is sought in ANDA No. 209457 would actively induce and contribute to infringement of the '677 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

58. Upon information and belief, as part of the ANDA filing, Defendants purportedly provided written certification to FDA that the claims of the '677 Patent are invalid and/or will not be infringed by the manufacture, use, or sale of Defendants' generic version of VASCEPA®.

59. Defendants gave written notice of their certification of invalidity and/or non-infringement of the '677 Patent, alleging that claims of the '677 Patent are invalid and/or that certain claims would not be infringed by Defendants' generic version of VASCEPA®, and informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '677 Patent.

60. Defendants have infringed the '677 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 209457 with a paragraph IV certification and seeking FDA

approval of ANDA No. 209457 to market a generic version of VASCEPA® prior to the expiration of the '677 Patent. Moreover, if Defendants commercially use, offer for sale, or sell their generic version of VASCEPA®, or induce or contribute to such conduct, they would further infringe the '677 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

61. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to infringement of the '677 Patent. Plaintiffs do not have an adequate remedy at law.

Count IV: Patent Infringement of the '652 Patent

62. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 61 above.

63. United States Patent No. 8,367,652, entitled "METHODS OF TREATING HYPERTRIGLYCERIDEMIA," was duly and legally issued by the United States Patent and Trademark Office on February 5, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the owner of the '652 Patent. A true and complete copy of the '652 Patent is attached hereto as Exhibit E.

64. Upon information and belief, Defendants submitted ANDA No. 209457 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of VASCEPA® before the expiration of the '652 Patent.

65. Defendants' manufacture, use, offer for sale, or sale of such product would infringe the claims of the '652 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

66. Upon information and belief, if approved, the generic VASCEPA® product for which approval is sought in Defendants' ANDA No. 209457 will be administered to human patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. This administration by, for example, physicians would constitute direct infringement, either literally or under the doctrine of equivalents, of one or more claims of the '652 Patent. Upon information and belief, this infringement will occur at Defendants' behest, with their intent, knowledge, and encouragement as a result of, for example, Defendants' sales,

marketing, and distribution of their ANDA Product as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons, Defendants will actively induce, encourage, aid, and abet administration of the generic VASCEPA® product with knowledge that it is in contravention of Plaintiffs' rights under the '652 Patent.

67. Defendants' manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the generic VASCEPA® product for which approval is sought in ANDA No. 209457 would actively induce and contribute to infringement of the '652 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

68. Upon information and belief, as part of the ANDA filing, Defendants purportedly provided written certification to FDA that the claims of the '652 Patent are invalid and/or will not be infringed by the manufacture, use, or sale of Defendants' generic version of VASCEPA®.

69. Defendants gave written notice of their certification of invalidity and/or non-infringement of the '652 Patent, alleging that claims of the '652 Patent are invalid and/or that certain claims would not be infringed by Defendants' generic version of VASCEPA®, and informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '652 Patent.

70. Defendants have infringed the '652 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 209457 with a paragraph IV certification and seeking FDA approval of ANDA No. 209457 to market a generic version of VASCEPA® prior to the expiration of the '652 Patent. Moreover, if Defendants commercially use, offer for sale, or sell their generic version of VASCEPA®, or induce or contribute to such conduct, they would further infringe the '652 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

71. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to infringement of the '652 Patent. Plaintiffs do

not have an adequate remedy at law.

Count V: Patent Infringement of the '920 Patent

72. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 71 above.

73. United States Patent No. 8,377,920, entitled "METHODS OF TREATING HYPERTRIGLYCERIDEMIA," was duly and legally issued by the United States Patent and Trademark Office on February 19, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the owner of the '920 Patent. A true and complete copy of the '920 Patent is attached hereto as Exhibit F.

74. Upon information and belief, Defendants submitted ANDA No. 209457 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of VASCEPA® before the expiration of the '920 Patent.

75. Defendants' manufacture, use, offer for sale, or sale of such product would infringe the claims of the '920 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

76. Upon information and belief, if approved, the generic VASCEPA® product for which approval is sought in Defendants' ANDA No. 209457 will be administered to human patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. This administration by, for example, physicians would constitute direct infringement, either literally or under the doctrine of equivalents, of one or more claims of the '920 Patent. Upon information and belief, this infringement will occur at Defendants' behest, with their intent, knowledge, and encouragement as a result of, for example, Defendants' sales, marketing, and distribution of their ANDA Product as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons, Defendants will actively induce, encourage, aid, and abet administration of the generic VASCEPA® product with knowledge that it is in contravention of Plaintiffs' rights under the '920 Patent.

77. Defendants' manufacture, use, offer for sale, or sale in the United States, or

importation into the United States, of the generic VASCEPA® product for which approval is sought in ANDA No. 209457 would actively induce and contribute to infringement of the '920 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

78. Upon information and belief, as part of the ANDA filing, Defendants purportedly provided written certification to FDA that the claims of the '920 Patent are invalid and/or will not be infringed by the manufacture, use, or sale of Defendants' generic version of VASCEPA®.

79. Defendants gave written notice of their certification of invalidity and/or non-infringement of the '920 Patent, alleging that claims of the '920 Patent are invalid and/or that certain claims would not be infringed by Defendants' generic version of VASCEPA®, and informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '920 Patent.

80. Defendants have infringed the '920 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 209457 with a paragraph IV certification and seeking FDA approval of ANDA No. 209457 to market a generic version of VASCEPA® prior to the expiration of the '920 Patent. Moreover, if Defendants commercially use, offer for sale, or sell their generic version of VASCEPA®, or induce or contribute to such conduct, they would further infringe the '920 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

81. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to infringement of the '920 Patent. Plaintiffs do not have an adequate remedy at law.

Count VI: Patent Infringement of the '446 Patent

82. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 81 above.

83. United States Patent No. 8,399,446, entitled "METHODS OF TREATING HYPERTRIGLYCERIDEMIA," was duly and legally issued by the United States Patent and

Trademark Office on March 19, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the owner of the '446 Patent. A true and complete copy of the '446 Patent is attached hereto as Exhibit G.

84. Upon information and belief, Defendants submitted ANDA No. 209457 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of VASCEPA® before the expiration of the '446 Patent.

85. Defendants' manufacture, use, offer for sale, or sale of such product would infringe the claims of the '446 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

86. Upon information and belief, if approved, the generic VASCEPA® product for which approval is sought in Defendants' ANDA No. 209457 will be administered to human patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. This administration by, for example, physicians would constitute direct infringement, either literally or under the doctrine of equivalents, of one or more claims of the '446 Patent. Upon information and belief, this infringement will occur at Defendants' behest, with their intent, knowledge, and encouragement as a result of, for example, Defendants' sales, marketing, and distribution of their ANDA Product as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons, Defendants will actively induce, encourage, aid, and abet administration of the generic VASCEPA® product with knowledge that it is in contravention of Plaintiffs' rights under the '446 Patent.

87. Defendants' manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the generic VASCEPA® product for which approval is sought in ANDA No. 209457 would actively induce and contribute to infringement of the '446 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

88. Upon information and belief, as part of the ANDA filing, Defendants purportedly provided written certification to FDA that the claims of the '446 Patent are invalid and/or will not be infringed by the manufacture, use, or sale of Defendants' generic version of

VASCEPA®.

89. Defendants gave written notice of their certification of invalidity and/or non-infringement of the '446 Patent, alleging that claims of the '446 Patent are invalid and/or that certain claims would not be infringed by Defendants' generic version of VASCEPA®, and informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '446 Patent.

90. Defendants have infringed the '446 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 209457 with a paragraph IV certification and seeking FDA approval of ANDA No. 209457 to market a generic version of VASCEPA® prior to the expiration of the '446 Patent. Moreover, if Defendants commercially use, offer for sale, or sell their generic version of VASCEPA®, or induce or contribute to such conduct, they would further infringe the '446 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

91. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to infringement of the '446 Patent. Plaintiffs do not have an adequate remedy at law.

Count VII: Patent Infringement of the '335 Patent

92. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 91 above.

93. United States Patent No. 8,415,335, entitled "METHODS OF TREATING HYPERTRIGLYCERIDEMIA," was duly and legally issued by the United States Patent and Trademark Office on April 9, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the owner of the '335 Patent. A true and complete copy of the '335 Patent is attached hereto as Exhibit H.

94. Upon information and belief, Defendants submitted ANDA No. 209457 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of VASCEPA® before the expiration of the '335 Patent.

95. Defendants' manufacture, use, offer for sale, or sale of such product would infringe the claims of the '335 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

96. Upon information and belief, if approved, the generic VASCEPA® product for which approval is sought in Defendants' ANDA No. 209457 will be administered to human patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. This administration by, for example, physicians would constitute direct infringement, either literally or under the doctrine of equivalents, of one or more claims of the '335 Patent. Upon information and belief, this infringement will occur at Defendants' behest, with their intent, knowledge, and encouragement as a result of, for example, Defendants' sales, marketing, and distribution of their ANDA Product as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons, Defendants will actively induce, encourage, aid, and abet administration of the generic VASCEPA® product with knowledge that it is in contravention of Plaintiffs' rights under the '335 Patent.

97. Defendants' manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the generic VASCEPA® product for which approval is sought in ANDA No. 209457 would actively induce and contribute to infringement of the '335 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

98. Upon information and belief, as part of the ANDA filing, Defendants purportedly provided written certification to FDA that the claims of the '335 Patent are invalid and/or will not be infringed by the manufacture, use, or sale of Defendants' generic version of VASCEPA®.

99. Defendants gave written notice of their certification of invalidity and/or non-infringement of the '335 Patent, alleging that claims of the '335 Patent are invalid and/or that certain claims would not be infringed by Defendants' generic version of VASCEPA®, and informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '335

Patent.

100. Defendants have infringed the '335 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 209457 with a paragraph IV certification and seeking FDA approval of ANDA No. 209457 to market a generic version of VASCEPA® prior to the expiration of the '335 Patent. Moreover, if Defendants commercially use, offer for sale, or sell their generic version of VASCEPA®, or induce or contribute to such conduct, they would further infringe the '335 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

101. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to infringement of the '335 Patent. Plaintiffs do not have an adequate remedy at law.

Count VIII: Patent Infringement of the '399 Patent

102. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 101 above.

103. United States Patent No. 8,426,399, entitled "METHODS OF TREATING HYPERTRIGLYCERIDEMIA," was duly and legally issued by the United States Patent and Trademark Office on April 23, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the owner of the '399 Patent. A true and complete copy of the '399 Patent along with the certificate of correction is attached hereto as Exhibit I.

104. Upon information and belief, Defendants submitted ANDA No. 209457 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of VASCEPA® before the expiration of the '399 Patent.

105. Defendants' manufacture, use, offer for sale, or sale of such product would infringe the claims of the '399 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

106. Upon information and belief, if approved, the generic VASCEPA® product for which approval is sought in Defendants' ANDA No. 209457 will be administered to human patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. This administration by, for example, physicians would constitute direct

infringement, either literally or under the doctrine of equivalents, of one or more claims of the '399 Patent. Upon information and belief, this infringement will occur at Defendants' behest, with their intent, knowledge, and encouragement as a result of, for example, Defendants' sales, marketing, and distribution of their ANDA Product as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons, Defendants will actively induce, encourage, aid, and abet administration of the generic VASCEPA® product with knowledge that it is in contravention of Plaintiffs' rights under the '399 Patent.

107. Defendants' manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the generic VASCEPA® product for which approval is sought in ANDA No. 209457 would actively induce and contribute to infringement of the '399 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

108. Upon information and belief, as part of the ANDA filing, Defendants purportedly provided written certification to FDA that the claims of the '399 Patent are invalid and/or will not be infringed by the manufacture, use, or sale of Defendants' generic version of VASCEPA®.

109. Defendants gave written notice of their certification of invalidity and/or non-infringement of the '399 Patent, alleging that claims of the '399 Patent are invalid and/or that certain claims would not be infringed by Defendants' generic version of VASCEPA®, and informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '399 Patent.

110. Defendants have infringed the '399 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 209457 with a paragraph IV certification and seeking FDA approval of ANDA No. 209457 to market a generic version of VASCEPA® prior to the expiration of the '399 Patent. Moreover, if Defendants commercially use, offer for sale, or sell their generic version of VASCEPA®, or induce or contribute to such conduct, they would

further infringe the '399 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

111. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to infringement of the '399 Patent. Plaintiffs do not have an adequate remedy at law.

Count IX: Patent Infringement of the '560 Patent

112. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 111 above.

113. United States Patent No. 8,431,560, entitled "METHODS OF TREATING HYPERTRIGLYCERIDEMIA," was duly and legally issued by the United States Patent and Trademark Office on April 30, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the owner of the '560 Patent. A true and complete copy of the '560 Patent is attached hereto as Exhibit J.

114. Upon information and belief, Defendants submitted ANDA No. 209457 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of VASCEPA® before the expiration of the '560 Patent.

115. Defendants' manufacture, use, offer for sale, or sale of such product would infringe the claims of the '560 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

116. Upon information and belief, if approved, the generic VASCEPA® product for which approval is sought in Defendants' ANDA No. 209457 will be administered to human patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. This administration by, for example, physicians would constitute direct infringement, either literally or under the doctrine of equivalents, of one or more claims of the '560 Patent. Upon information and belief, this infringement will occur at Defendants' behest, with their intent, knowledge, and encouragement as a result of, for example, Defendants' sales, marketing, and distribution of their ANDA Product as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons, Defendants will actively induce, encourage, aid, and abet administration of the generic

VASCEPA® product with knowledge that it is in contravention of Plaintiffs' rights under the '560 Patent.

117. Defendants' manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the generic VASCEPA® product for which approval is sought in ANDA No. 209457 would actively induce and contribute to infringement of the '560 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

118. Upon information and belief, as part of the ANDA filing, Defendants purportedly provided written certification to FDA that the claims of the '560 Patent are invalid and/or will not be infringed by the manufacture, use, or sale of Defendants' generic version of VASCEPA®.

119. Defendants gave written notice of their certification of invalidity and/or non-infringement of the '560 Patent, alleging that claims of the '560 Patent are invalid and/or that certain claims would not be infringed by Defendants' generic version of VASCEPA®, and informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '560 Patent.

120. Defendants have infringed the '560 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 209457 with a paragraph IV certification and seeking FDA approval of ANDA No. 209457 to market a generic version of VASCEPA® prior to the expiration of the '560 Patent. Moreover, if Defendants commercially use, offer for sale, or sell their generic version of VASCEPA®, or induce or contribute to such conduct, they would further infringe the '560 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

121. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to infringement of the '560 Patent. Plaintiffs do not have an adequate remedy at law.

Count X: Patent Infringement of the '650 Patent

122. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to

121 above.

123. United States Patent No. 8,440,650, entitled "METHODS OF TREATING HYPERTRIGLYCERIDEMIA," was duly and legally issued by the United States Patent and Trademark Office on May 14, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the owner of the '650 Patent. A true and complete copy of the '650 Patent is attached hereto as Exhibit K.

124. Upon information and belief, Defendants submitted ANDA No. 209457 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of VASCEPA® before the expiration of the '650 Patent.

125. Defendants' manufacture, use, offer for sale, or sale of such product would infringe the claims of the '650 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

126. Upon information and belief, if approved, the generic VASCEPA® product for which approval is sought in Defendants' ANDA No. 209457 will be administered to human patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. This administration by, for example, physicians would constitute direct infringement, either literally or under the doctrine of equivalents, of one or more claims of the '650 Patent. Upon information and belief, this infringement will occur at Defendants' behest, with their intent, knowledge, and encouragement as a result of, for example, Defendants' sales, marketing, and distribution of their ANDA Product as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons, Defendants will actively induce, encourage, aid, and abet administration of the generic VASCEPA® product with knowledge that it is in contravention of Plaintiffs' rights under the '650 Patent.

127. Defendants' manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the generic VASCEPA® product for which approval is sought in ANDA No. 209457 would actively induce and contribute to infringement of the '650 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

128. Upon information and belief, as part of the ANDA filing, Defendants purportedly provided written certification to FDA that the claims of the '650 Patent are invalid and/or will not be infringed by the manufacture, use, or sale of Defendants' generic version of VASCEPA®.

129. Defendants gave written notice of their certification of invalidity and/or non-infringement of the '650 Patent, alleging that claims of the '650 Patent are invalid and/or that certain claims would not be infringed by Defendants' generic version of VASCEPA®, and informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '650 Patent.

130. Defendants have infringed the '650 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 209457 with a paragraph IV certification and seeking FDA approval of ANDA No. 209457 to market a generic version of VASCEPA® prior to the expiration of the '650 Patent. Moreover, if Defendants commercially use, offer for sale, or sell their generic version of VASCEPA®, or induce or contribute to such conduct, they would further infringe the '650 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

131. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to infringement of the '650 Patent. Plaintiffs do not have an adequate remedy at law.

Count XI: Patent Infringement of the '929 Patent

132. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 131 above.

133. United States Patent No. 8,518,929, entitled "METHODS OF TREATING HYPERTRIGLYCERIDEMIA," was duly and legally issued by the United States Patent and Trademark Office on August 27, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the owner of the '929 Patent. A true and complete copy of the '929 Patent is attached hereto as Exhibit L.

134. Upon information and belief, Defendants submitted ANDA No. 209457 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of VASCEPA® before the expiration of the '929 Patent.

135. Defendants' manufacture, use, offer for sale, or sale of such product would infringe the claims of the '929 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

136. Upon information and belief, if approved, the generic VASCEPA® product for which approval is sought in Defendants' ANDA No. 209457 will be administered to human patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. This administration by, for example, physicians would constitute direct infringement, either literally or under the doctrine of equivalents, of one or more claims of the '929 Patent. Upon information and belief, this infringement will occur at Defendants' behest, with their intent, knowledge, and encouragement as a result of, for example, Defendants' sales, marketing, and distribution of their ANDA Product as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons, Defendants will actively induce, encourage, aid, and abet administration of the generic VASCEPA® product with knowledge that it is in contravention of Plaintiffs' rights under the '929 Patent.

137. Defendants' manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the generic VASCEPA® product for which approval is sought in ANDA No. 209457 would actively induce and contribute to infringement of the '929 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

138. Upon information and belief, as part of the ANDA filing, Defendants purportedly provided written certification to FDA that the claims of the '929 Patent are invalid and/or will not be infringed by the manufacture, use, or sale of Defendants' generic version of VASCEPA®.

139. Defendants gave written notice of their certification of invalidity and/or non-infringement of the '929 Patent, alleging that claims of the '929 Patent are invalid and/or that

certain claims would not be infringed by Defendants' generic version of VASCEPA®, and informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '929 Patent.

140. Defendants have infringed the '929 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 209457 with a paragraph IV certification and seeking FDA approval of ANDA No. 209457 to market a generic version of VASCEPA® prior to the expiration of the '929 Patent. Moreover, if Defendants commercially use, offer for sale, or sell their generic version of VASCEPA®, or induce or contribute to such conduct, they would further infringe the '929 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

141. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to infringement of the '929 Patent. Plaintiffs do not have an adequate remedy at law.

Count XII: Patent Infringement of the '698 Patent

142. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 141 above.

143. United States Patent No. 8,524,698, entitled "METHODS OF TREATING HYPERTRIGLYCERIDEMIA," was duly and legally issued by the United States Patent and Trademark Office on September 3, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the owner of the '698 Patent. A true and complete copy of the '698 Patent along with the certificate of correction is attached hereto as Exhibit M.

144. Upon information and belief, Defendants submitted ANDA No. 209457 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of VASCEPA® before the expiration of the '698 Patent.

145. Defendants' manufacture, use, offer for sale, or sale of such product would infringe the claims of the '698 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

146. Upon information and belief, if approved, the generic VASCEPA® product for

which approval is sought in Defendants' ANDA No. 209457 will be administered to human patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. This administration by, for example, physicians would constitute direct infringement, either literally or under the doctrine of equivalents, of one or more claims of the '698 Patent. Upon information and belief, this infringement will occur at Defendants' behest, with their intent, knowledge, and encouragement as a result of, for example, Defendants' sales, marketing, and distribution of their ANDA Product as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons, Defendants will actively induce, encourage, aid, and abet administration of the generic VASCEPA® product with knowledge that it is in contravention of Plaintiffs' rights under the '698 Patent.

147. Defendants' manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the generic VASCEPA® product for which approval is sought in ANDA No. 209457 would actively induce and contribute to infringement of the '698 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

148. Upon information and belief, as part of the ANDA filing, Defendants purportedly provided written certification to FDA that the claims of the '698 Patent are invalid and/or will not be infringed by the manufacture, use, or sale of Defendants' generic version of VASCEPA®.

149. Defendants gave written notice of their certification of invalidity and/or non-infringement of the '698 Patent, alleging that claims of the '698 Patent are invalid and/or that certain claims would not be infringed by Defendants' generic version of VASCEPA®, and informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '698 Patent.

150. Defendants have infringed the '698 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 209457 with a paragraph IV certification and seeking FDA

approval of ANDA No. 209457 to market a generic version of VASCEPA® prior to the expiration of the '698 Patent. Moreover, if Defendants commercially use, offer for sale, or sell their generic version of VASCEPA®, or induce or contribute to such conduct, they would further infringe the '698 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

151. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to infringement of the '698 Patent. Plaintiffs do not have an adequate remedy at law.

Count XIII: Patent Infringement of the '372 Patent

152. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 151 above.

153. United States Patent No. 8,546,372, entitled "METHODS OF TREATING HYPERTRIGLYCERIDEMIA," was duly and legally issued by the United States Patent and Trademark Office on October 1, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the owner of the '372 Patent. A true and complete copy of the '372 Patent is attached hereto as Exhibit N.

154. Upon information and belief, Defendants submitted ANDA No. 209457 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of VASCEPA® before the expiration of the '372 Patent.

155. Defendants' manufacture, use, offer for sale, or sale of such product would infringe the claims of the '372 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

156. Upon information and belief, if approved, the generic VASCEPA® product for which approval is sought in Defendants' ANDA No. 209457 will be administered to human patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. This administration by, for example, physicians would constitute direct infringement, either literally or under the doctrine of equivalents, of one or more claims of the '372 Patent. Upon information and belief, this infringement will occur at Defendants' behest, with their intent, knowledge, and encouragement as a result of, for example, Defendants' sales,

marketing, and distribution of their ANDA Product as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons, Defendants will actively induce, encourage, aid, and abet administration of the generic VASCEPA® product with knowledge that it is in contravention of Plaintiffs' rights under the '372 Patent.

157. Defendants' manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the generic VASCEPA® product for which approval is sought in ANDA No. 209457 would actively induce and contribute to infringement of the '372 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

158. Upon information and belief, as part of the ANDA filing, Defendants purportedly provided written certification to FDA that the claims of the '372 Patent are invalid and/or will not be infringed by the manufacture, use, or sale of Defendants' generic version of VASCEPA®.

159. Defendants gave written notice of their certification of invalidity and/or non-infringement of the '372 Patent, alleging that claims of the '372 Patent are invalid and/or that certain claims would not be infringed by Defendants' generic version of VASCEPA®, and informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '372 Patent.

160. Defendants have infringed the '372 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 209457 with a paragraph IV certification and seeking FDA approval of ANDA No. 209457 to market a generic version of VASCEPA® prior to the expiration of the '372 Patent. Moreover, if Defendants commercially use, offer for sale, or sell their generic version of VASCEPA®, or induce or contribute to such conduct, they would further infringe the '372 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

161. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to infringement of the '372 Patent. Plaintiffs do

not have an adequate remedy at law.

Count XIV: Patent Infringement of the '594 Patent

162. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 161 above.

163. United States Patent No. 8,617,594, entitled "STABLE PHARMACEUTICAL COMPOSITION AND METHODS OF USING SAME," was duly and legally issued by the United States Patent and Trademark Office on December 31, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the owner of the '594 Patent. A true and complete copy of the '594 Patent is attached hereto as Exhibit O.

164. Upon information and belief, Defendants submitted ANDA No. 209457 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of VASCEPA® before the expiration of the '594 Patent.

165. Defendants' manufacture, use, offer for sale, or sale of such product would infringe the claims of the '594 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

166. Upon information and belief, if approved, the generic VASCEPA® product for which approval is sought in Defendants' ANDA No. 209457 will be administered to human patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. This administration by, for example, physicians would constitute direct infringement, either literally or under the doctrine of equivalents, of one or more claims of the '594 Patent. Upon information and belief, this infringement will occur at Defendants' behest, with their intent, knowledge, and encouragement as a result of, for example, Defendants' sales, marketing, and distribution of their ANDA Product as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons, Defendants will actively induce, encourage, aid, and abet administration of the generic VASCEPA® product with knowledge that it is in contravention of Plaintiffs' rights under the '594 Patent.

167. Defendants' manufacture, use, offer for sale, or sale in the United States, or

importation into the United States, of the generic VASCEPA® product for which approval is sought in ANDA No. 209457 would actively induce and contribute to infringement of the '594 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

168. Upon information and belief, as part of the ANDA filing, Defendants purportedly provided written certification to FDA that the claims of the '594 Patent are invalid and/or will not be infringed by the manufacture, use, or sale of Defendants' generic version of VASCEPA®.

169. Defendants gave written notice of their certification of invalidity and/or non-infringement of the '594 Patent, alleging that claims of the '594 Patent are invalid and/or that certain claims would not be infringed by Defendants' generic version of VASCEPA®, and informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '594 Patent.

170. Defendants have infringed the '594 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 209457 with a paragraph IV certification and seeking FDA approval of ANDA No. 209457 to market a generic version of VASCEPA® prior to the expiration of the '594 Patent. Moreover, if Defendants commercially use, offer for sale, or sell their generic version of VASCEPA®, or induce or contribute to such conduct, they would further infringe the '594 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

171. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to infringement of the '594 Patent. Plaintiffs do not have an adequate remedy at law.

Prayer for Relief

WHEREFORE, Plaintiffs seek the following relief:

A. A judgment that Defendants have infringed the '728, '715, '677, '652, '920, '446, '335, '399, '560, '650, '929, '698, '372, and '594 Patents under 35 U.S.C. § 271(e)(2)(A);

B. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of

any FDA approval of ANDA No. 209457 is not earlier than the expiration date of the '728, '715, '677, '652, '920, '446, '335, '399, '560, '650, '929, '698, '372, and '594 Patents, or any later expiration of exclusivity for the '728, '715, '677, '652, '920, '446, '335, '399, '560, '650, '929, '698, '372, and '594 Patents to which Plaintiffs are or become entitled;

C. A permanent injunction restraining and enjoining Defendants and their officers, agents, servants, employees, parents, subsidiaries, divisions, affiliates, and those persons in active concert or participation with any of them, from making, using, selling, offering to sell, or importing any product that infringes the '728, '715, '677, '652, '920, '446, '335, '399, '560, '650, '929, '698, '372, and '594 Patents, including the product described in ANDA No. 209457;

D. A judgment declaring that making, using, selling, offering to sell, or importing the product described in ANDA No. 209457, or inducing or contributing to such conduct, would constitute infringement of the '728, '715, '677, '652, '920, '446, '335, '399, '560, '650, '929, '698, '372, and '594 Patents by Defendants pursuant to 35 U.S.C. § 271(a), (b), and/or (c);

E. A finding that this is an exceptional case, and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;

F. Costs and expenses in this action; and

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G. Such further and other relief as this Court determines to be just and proper.

DATED: October 31, 2016

Respectfully submitted,

/s/ Nicholas J. Santoro

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